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VICE PRESIDENT
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**American
Chemistry
Council**
*Good Chemistry
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April 3, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Proposed Regulations on Prior Notice of Imported Food Under Public Health Security and Bioterrorism Preparedness and Response Act of 2002, **Docket No. 02N-0278**

The American Chemistry Council (ACC) Biocides Panel (Panel) is submitting these comments on behalf of its 46 member companies. A list of the Panel's members is attached. Panel members are engaged in the manufacture, formulation, distribution and sale of antimicrobial active ingredients and formulated end use products registered and regulated by EPA as pesticides pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Some of these EPA-registered antimicrobial pesticides also are regulated by FDA as food additives pursuant to FFDCA section 409 and others are also regulated by EPA as pesticide chemical residues pursuant to FFDCA section 408. The Panel appreciates this opportunity to comment and urges FDA to consider these comments in its continuing deliberations.

As discussed more fully below, the Panel requests FDA to clarify that this regulation requiring prior notice of import is not applicable to antimicrobial pesticides with FDA and/or EPA approval for food contact use. EPA already requires prior notification of each pesticide import. Of even greater significance, *EPA must explicitly approve each pesticide import prior to its arrival*. FDA's inclusion of antimicrobial pesticides within the scope of this regulation would impose unnecessary burdens on antimicrobial pesticide registrants, but without meaningfully enhancing protection of the food supply.

The regulation proposed to be codified at 21 CFR 1.227 defines "food" as the term is defined in FFDCA section 201(f). The regulation also provides an extensive list of examples of what constitutes food for purposes of this rule. The list includes "additives, including substances that migrate into food from food packaging and other articles that contact food." The inclusion of the term "additives" has the effect of extending the definition of food to "substances, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food." 21 CFR § 170.3(e)(1). As a consequence, the proposed regulation, as written, applies to any antimicrobial pesticide that ultimately may contact or be incorporated into an article that contacts food by "indirect" or "secondary direct" means, consistent with existing, explicit FDA and/or EPA approval.

Such substances are not themselves food and are not intended to become part of food. Nonetheless, because some migration to food from their use may occur, FDA regulates food contact uses pursuant to FFDCA section 409 and 21 CFR parts 173 through 178. There are numerous FDA approved food additive uses of antimicrobial pesticides. For example, antimicrobials used in fruit and vegetable rinses in food processing facilities and in beet and cane sugar mills to control pathogenic and spoilage microorganisms are regulated as secondary direct food additives. Antimicrobial slimicides used to



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that may come in contact with food; for example, adhesives in food packaging, paper and packaging coatings, and various polymers (e.g., those used in conveyer belts in food processing facilities, restaurant equipment, dairy and milking equipment) are regulated as indirect food additives. Antimicrobial preservatives are used in these and numerous other manufactured goods and articles, including those that may contact food, to protect the articles from deterioration. Preservation is necessary to extend the useful life of such goods, resulting in significant consumer benefits, economic savings and resource conservation.

EPA regulates antimicrobials intended for use on food-contact hard surfaces as pesticide chemical residues. These antimicrobials are not applied to food. Instead they are used to control pathogenic microorganisms on hard surfaces that contact foods. Prior to 1996 they were regulated by FDA as indirect food additives. They continue to meet the definition of food additive, in that their presence in food would occur only by migration from a treated surface to food. Therefore, it is possible that antimicrobials registered for these uses also could be subject to the regulation.

Ironically, other pesticide chemicals that are applied *directly* to food as it is grown or stored would *not* be subject to the prior notification requirement because their uses do not fall within the definition of food "additive." The Panel does not believe that FDA intended its proposal to create this incongruous result.

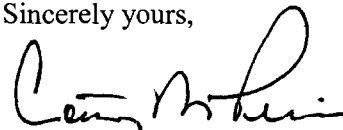
Including antimicrobial pesticides within the scope of this proposal is not only inappropriate, but also unnecessary. Pesticides are imported pursuant to FIFRA, not FFDCA. All pesticide imports, including antimicrobial pesticides, are subject to *prior approval* by EPA before they are admitted to the US. Each importer must submit EPA Form No 3540-1, Notice of Arrival of Pesticides and Devices (NOA), to EPA prior to arrival of the pesticide shipment and *obtain EPA's explicit approval for such import*. 19 CFR 12.112. U.S. Customs may not grant entry unless the importer or agent presents the NOA that has been signed as approved by the EPA Regional official with responsibility for the particular port of entry *and* the Customs officer has confirmed that the shipment is consistent with the EPA NOA form. A copy of the NOA form and instructions for completion is attached.

In conclusion, the Panel requests that FDA clarify that this regulation requiring prior notice of import is not applicable to antimicrobial pesticides with FDA and/or EPA approved food contact uses. Such regulation is unnecessary. EPA stringently regulates antimicrobial pesticide imports, and explicitly approves each shipment prior to its entry to the US. FDA's inclusion of antimicrobial pesticides within the scope of this regulation would impose unnecessary burdens on antimicrobial pesticide registrants without enhancing protection of the food supply.

If you have any questions regarding these comments or related issues, please do not hesitate to Dr. Hasmukh C. Shah of my staff at 703-741-5637.

Attachment

Sincerely yours,




Courtney M. Price
Vice President, CHEMSTAR

cc: Stuart Shapiro (OMB)

**American Chemistry Council
Biocides Panel Member Companies**

3M
Acti-Chem Specialties
AEGIS Environments
Akzo Nobel Chemicals, Inc.
Albemarle Corporation
Alcide Corporation
Ameribrom, Inc.
Arch Chemicals, Inc.
Ashland Chemical
Avecia Inc.
BASF Corporation
Bayer Corporation
Bayer CropScience
Bio-Lab, Inc.
Buckman Laboratories
Chemical Specialties, Inc.
Ciba Specialty Chemicals
The Clorox Company
Dow
DuPont
Ecolab Inc.
Elementis Chromium LP
FMC Corporation
Hercules Incorporated
International Specialty Products
ISK Biocides, Inc.
J.H. Baxter & Company
Janssen Pharmaceutica
JohnsonDiversey Inc.
Kemira Chemicals, Inc.
Lonza Inc.
The Lubrizol Corporation
Mason Chemical Company
Microban Products Company
Milliken Chemical
ONDEO Nalco Company
Osmose, Inc.
Phibro-Tech
The Procter and Gamble Company
Reckitt Benckiser Inc.
Rhodia Inc.
Rohm and Haas Company
SC Johnson & Son, Inc.
Stepan Company
Troy Chemical Corporation
Verichem

 <p>United States Environmental Protection Agency Washington, DC 20460</p> <p>Notice of Arrival of Pesticides and Devices</p>		<p>Send Completed Form to Appropriate Regional Office Listed on the Reverse of this Form.</p>		<p>Form Approved OMB No. 2070-0020</p>	
<p>Note: Read Instructions on reverse before completing form.</p>					
<p>Part I: To Be Completed by Importer or Agent</p>					
1. Name and Complete Address of Broker or Agent			2. Name and Complete Address of Importer or Consignee		
<input type="checkbox"/> Return Form to this Address			<input type="checkbox"/> Return Form to this Address		
3. Name and Address of Shipper			4. EPA Registration Number		5. EPA Producer Establishment No.
			6. Brand name of Product		
7. Major Active Ingredients and Percentage of Each					
8. Unit Size	9. Quantity	10. Total Net Weight	11. Country of Origin		
12. Port of Entry			13. Carrier		
14. Entry Number		15. Entry Date	16. I assert that information constituting Confidential Business Information is shown in the above blocks numbered: (Note: Blocks 4, 5, 6, 7 are not entitled to CBI treatment—see Instructions)		
17. Location of Goods for Examination after Importation					
18. Remarks					
<p>Certification</p> <p>I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.</p>					
19. Printed Name of Importer or Agent		Telephone Number	20. Signature of Importer or Agent		Date Signed
<p>Part II: To Be Completed by U.S. Environmental Protection Agency</p>					
<p>Action to be taken by U.S. Customs Service</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 30%;"> <input type="checkbox"/> Release Shipment </div> <div style="width: 30%;"> <input type="checkbox"/> Detain for Inspection </div> <div style="width: 30%;"> <input type="checkbox"/> Release shipment to consignee under bond. Shipment must </div> </div> <div style="margin-top: 5px;"> <input type="checkbox"/> Other (Specify) </div>					
Remarks					
Signature and Title of EPA Official					Date
<p>Part III: To Be Completed by U.S. Customs Service</p>					
<p>The information shown in Part I was compared with the entry papers for this shipment and no discrepancies were noted. The shipment was handled as instructed by EPA in Part II. Any deviations should be brought to the attention of EPA before releasing shipment and</p>					
Remarks					
Signature of District Director of Customs					Date

Instructions

Customs Regulations. 19 CFR 12.112 requires an importer desiring to import pesticides or devices into the United States to submit EPA Form 3540-1, Notice of Arrival of Pesticides and Devices, to the U.S. Environmental Protection Agency prior to the arrival of shipment in the United States. This form will be used by:

Importer or Agent. The Importer or his agent must complete Part I of the form. It may be necessary to complete some of the items at the time of entry, e.g., entry data, carrier. To expedite the handling of pesticides shipments, submit this form to the EPA office listed below having jurisdiction over the state/territory in which the Port of Entry is located prior to the arrival of the shipment.

EPA. Part II of this form will be completed by EPA. EPA will retain the EPA Copy for its files and return the other copies to the importer or agent for presentation to Customs at the time of entry.

Customs. Customs will compare the information shown on this form with the entry documents and the shipment. Bring any discrepancies to the attention of EPA before the shipment is released and noted in the remarks section. If the importation is not handled by Customs in the manner instructed in Part II, this should also be noted in remarks. All data left blank by the importer (e.g., entry date) must be completed at this time. After completion of Part III and signing the form, Customs will return the Official File Copy to EPA and retain the Custom's Copy.

The following blocks are self explanatory - 1, 2, 8, 9, 10, 12, 14, 15, 18, 19, and 20.

3. Name and Address of Shipper. The name and address of person exporting the pesticide to the United States.

4. EPA Registration No. The product registration number assigned at the time of registration which identifies the product. If the product is a device, write the word 'device' in the block.

5. EPA Producer Establishment No. The producing establishment registration number which identified where the pesticidal product, active ingredient, or device was produced.

6. Brand Name of Product. Name under which the product is sold or distributed.

7. Major Active Ingredients and Percentage of Each. If block 4 contains registration number, leave blank. If no registration number, list active ingredients (or two major ingredients and percentage of each).

11. Country of Origin. The country in which the pesticide producer is located.

13. Carrier. E.g., ship's name, airline or trucking company.

16. Confidential Business Information (CBI) designation. Please note that the information provided in blocks 4, 5, 6, and 7 is not entitled to confidential treatment under section 7(d) of FIFRA and under labeling requirements for pesticides at 40 CFR 156.10. Information provided in those blocks will be made public with no further notice.

17. Location of Goods for Examination after Importation. Enter the EPA establishment number for importing registered establishment in the case of unregistered product imports between establishments operated by the same producer.

EPA Regional Offices	States Covered	EPA Regional Offices	States Covered
EPA Region I 1 Congress Street (SEA) Boston, MA 02114-2023	CT MA ME NH RI VT	EPA Region VI 1445 Ross Avenue Suite #1200 (6PD-P) Dallas, TX 75202-2733	AR LA NM OK TX
EPA Region II MS-500, Bldg #5 2890 Woodbridge Ave. Edison, NJ 08837-3679	NJ NY PR VI	EPA Region VII 901 N. 5 TH Street (PESTWWPD) Kansas City, KS 66101	IA KS MO NE
EPA Region III 1650 Arch Street (3WC32) Philadelphia, PA 19103-2029	DE DC MD PA VA WV	EPA Region VIII 999 18 th Street Suite #500 (8ENF/TEP) Denver, CO 80202-2466	CO MT ND SD UT WY
EPA Region IV 61 Forsyth Street, SW (APT-PS) Atlanta, GA 30303-8960	AL FL GA KY MS NC SC TN	EPA Region IX 75 Hawthorne Street (CMD-4-3) San Francisco, CA 94105-3901	AZ AS CA GU HI NV PI WK
EPA Region V 77 West Jackson Blvd.(DT-8J) Chicago, IL 60604-3507	IL IN OH MI MN WI	EPA Region X 1200 Sixth Avenue (ECO-084) Seattle, WA 98101-9797	AK ID OR WA